UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

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TIFFANY ONTIVEROS, Plaintiff(s), v. COLOPLAST CORP., et al., Defendant(s).	Case No. 2:20-CV-463 JCM (VCF) ORDER

Presently before the court are ten *Daubert* motions. (ECF Nos. 31–40). Plaintiff Tiffany Ontiveros ("plaintiff") filed five motions, (ECF Nos. 31–35), to which defendants Coloplast Corp. and Coloplast Manufacturing US, LLC (collectively "defendants") responded (ECF Nos. 48–52). Defendants filed the other five motions (ECF Nos. 36–40), to which plaintiff responded (ECF Nos. 42–46), and defendants replied (ECF Nos. 55–59).

Also before the court is defendants' motion for summary judgment. (ECF No. 41). Plaintiff filed a response (ECF No. 54), to which defendants replied (ECF No. 61).

Also before the court is defendants' motion for leave to file supplemental authority regarding two of their *Daubert* motions. (ECF No. 64). Plaintiff did not respond, and the time to do so has passed.

I. Background

This products liability lawsuit arises from injuries plaintiff sustained following her April 17, 2019, Altis Single-Incision Sling System ("Altis") implant. (ECF No. 1 ¶ 77). The Altis is a mid-urethral sling that is surgically implanted to treat stress urinary incontinence ("SUI"), and is designed and manufactured by defendants. Plaintiff alleges that after her implant, she suffered

pelvic and vaginal pain, "extrusion and erosion of the mesh," chronic inflammation, mesh adhesion, failure to treat her SUI, and contraction of the mesh. (*Id.* at ¶ 79.).

On September 30, 2019, plaintiff underwent a revision procedure to remove the Altis, after which time her pain subsided. (*Id.*). On March 5, 2020, she filed this lawsuit alleging claims for negligence, negligent misrepresentation, gross negligence, "strict liability – design defect," "strict liability – failure to warn," "strict liability – manufacturing defect," "discovery rule, tolling and fraudulent concealment," violation of the Nevada Deceptive Trade Practices Act, and punitive damages. (*See generally id.*).

Plaintiff and defendants offer several expert witnesses to support their claims and defenses. The parties now move to exclude or limit certain opinions and testimony of ten of those experts: Karen Christman, Ph.D. (ECF No. 31); Benny Dean Freeman, Ph.D., P.E. (ECF No. 32); Diana Molavi, M.D., Ph.D. (ECF No. 33); Emily Cole, M.D. (ECF No. 34); Karen Becker, Ph.D. (ECF No. 35); Bruce Rosenzweig, M.D. (ECF No. 36); Neeraj Kohli, M.D. (ECF No. 37); Peggy Pence, Ph.D. (ECF No. 38); Jimmy Mays, Ph.D. (ECF No. 39); And Michael Hibner M.D., Ph.D. (ECF No. 40).

Defendants also move for summary judgment on all of plaintiff's claims. (ECF No. 41). Plaintiff concedes that she will not be moving forward on several of her claims but argues that summary judgment should be denied on her claims for strict liability – design defect, negligence, and gross negligence. (*See* ECF No. 54).

II. Legal Standard

A. *Daubert* motions

Federal Rule of Evidence 702 controls the court's determination whether to strike a proposed expert witness:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and

> (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702; *see generally Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

"*Daubert*'s general holding—setting forth the trial judge's general 'gatekeeping' obligation—applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999). Though the court has broad discretion in discharging its gatekeeping obligation, *Daubert* provides a non-exhaustive list of relevant factors for consideration: "1) whether a theory or technique can be tested; 2) whether it has been subjected to peer review and publication; 3) the known or potential error rate of the theory or technique; and 4) whether the theory or technique enjoys general acceptance within the relevant scientific community." *United States v. Hankey*, 203 F.3d 1160, 1167 (9th Cir. 2000) (citing *Daubert*, 509 U.S. at 592–94).

Essentially, expert testimony must be relevant and reliable, and it must "relate to scientific, technical, or other specialized knowledge, which does not include unsupported speculation and subjective beliefs." *Guidroz–Brault v. Missouri Pac. R.R. Co.*, 254 F.3d 825, 829 (9th Cir. 2001). Therefore, exclusion of expert testimony is proper only when such testimony is irrelevant or unreliable because "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596 (citing *Rock v. Arkansas*, 483 U.S. 44, 61 (1987)).

B. Summary judgment

The Federal Rules of Civil Procedure allow summary judgment when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that "there is no genuine dispute as to any material fact and the movant is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(a). A principal purpose of summary judgment is "to isolate and dispose of factually unsupported claims." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–24 (1986).

For purposes of summary judgment, disputed factual issues should be construed in favor of the nonmoving party. *Lujan v. Nat'l Wildlife Fed.*, 497 U.S. 871, 888 (1990). However, to

withstand summary judgment, the nonmoving party must "set forth specific facts showing that there is a genuine issue for trial." *Id.*

In determining summary judgment, a court applies a burden-shifting analysis. "When the party moving for summary judgment would bear the burden of proof at trial, it must come forward with evidence which would entitle it to a directed verdict if the evidence went uncontroverted at trial. In such a case, the moving party has the initial burden of establishing the absence of a genuine issue of fact on each issue material to its case." *C.A.R. Transp. Brokerage Co. v. Darden Rests., Inc.*, 213 F.3d 474, 480 (9th Cir. 2000) (citations omitted).

If the moving party satisfies its initial burden, the burden then shifts to the opposing party to establish that a genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The opposing party need not establish a dispute of material fact conclusively in its favor. *See T.W. Elec. Serv., Inc. v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 631 (9th Cir. 1987). It is sufficient that "the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial." *Id.*

At summary judgment, a court's function is not to weigh the evidence and determine the truth, but to determine whether a genuine dispute exists for trial. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). The evidence of the nonmovant is "to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255. But if the evidence of the nonmoving party is merely colorable or is not significantly probative, summary judgment may be granted. *See id.* at 249–50.

III. Discussion

As an initial matter, defendants move for summary judgment on plaintiff's claims for negligent misrepresentation, strict liability – failure to warn, strict liability – manufacturing defect, fraudulent concealment, and violation of the Nevada Deceptive Trade Practices Act. (ECF No. 41). Plaintiff provides no arguments to support that those claims should survive defendants' motion. Instead, she concedes that "[u]nder the facts of this case and Nevada law, [she] will not be proceeding" on those claims. (ECF No. 52).

Plaintiff argues that defendants' motion should therefore be denied as moot as to those claims. The court disagrees. As plaintiff admits, her abandoned claims fail as a matter of law. Accordingly, summary judgment is granted in favor of defendants and against plaintiff on those claims. Thus, remaining before the court are plaintiff's claims for strict liability – design defect, negligence, and gross negligence.

Defendants argue that plaintiff cannot prevail on the remaining claims because her case-specific causation expert, Dr. Hibner, is not qualified to testify about the causation of her injuries. (ECF No. 41 at 4–6). Plaintiff does not specifically refute defendants' position, but instead argues that Dr. Hibner *is* qualified to testify about the cause of her injuries. (ECF No. 54 at 3–7). Defendants contend that plaintiff thus concedes her remaining claims rely on the admissibility of Dr. Hibner's causation testimony. (ECF No. 61 at 1–2). The court agrees.

Thus, the court first addresses defendants' *Daubert* motion to exclude Dr. Hibner's testimony. Consistent with the following, the court grants defendants' motion and plaintiff's remaining claims all fail as a matter of law.

A. Defendants' motion to exclude Dr. Hibner is granted

Defendants argue that "Dr. Hibner is unqualified to opine that the Altis's design caused the [p]laintiff's injuries because he has insufficient knowledge of the product's design properties." (ECF No. 40 at 5). They further argue that Dr. Hibner himself admitted that he has no relevant knowledge, training, or experience related to Altis' material or its design properties and that he is unaware of the design element that he believes is central to the Altis's alleged defect: its pore size. (*Id.*) (citing ECF No. 40-2 at 12–13).

Plaintiff argues that Dr. Hibner is more than qualified "to talk about the thickness of the mesh and how meshes that are less porous and [stiffer] . . . are less likely to incorporate into the tissue" and therefore caused plaintiff's injuries. (ECF No. 45 at 3). She further argues that other experts will cover the physics of the mesh in more detail, so Dr. Hibner need not be qualified to testify on that issue himself.

Additionally, plaintiff notes that Dr. Hibner reviewed the general causation reports for the Altis from Dr. Kohli and Dr. Rosenzweig, and "'performed a differential diagnosis that included

carefully reviewing and considering the patient's medical history, the type of mesh used, and attachment of the implant, as well as medical literature and relevant research,' including 'engineering data related to pelvic mesh' compiled in the other expert reports." (ECF No. 45 at 3–5) (quoting ECF No. 45-1 at 6, 14–15).

Finally, plaintiff argues that "[a]s 'a reviewer for several medical journals' Dr. Hibner is surely qualified to assess the methodology and findings in the literature he reviewed and form an opinion, that is draw a conclusion, based on his clinical experience treating mesh-related injuries." (*Id.*).

Defendants argue that those arguments fail to address whether Dr. Hibner is qualified to testify that the product's alleged *defect* specifically caused plaintiff's injuries. The court agrees.

Under Nevada law, to prevail on a claim of strict products liability for design defect, a plaintiff must prove that: 1) the defendant placed a defective product in the market; 2) the product was defective when it left the defendant's possession, and 3) the defect caused plaintiff's injuries. *Ford Motor Co. v. Trejo*, 402 P.3d 649, 653 (Nev. 2017) (citing *Shoshone Coca–Cola Bottling Co. v. Dolinski*, 420 P.2d 855, 857–58 (Nev. 1966)).

During his deposition, Dr. Hibner admitted that he was not an expert in the design of mesh slings. (ECF No. 40-2 at 11). He then stated that he planned to testify about how less porous and stiffer meshes are less likely to incorporate into the patients' tissues but represented that his opinion is primarily based on a single research project, the "Moalli paper." (*Id.*). He does not explain what methods were used for that paper or how the methods are reliable.

Dr. Hibner testified that to prepare for his deposition, he reviewed the general causation reports of two other experts—Dr. Kohli and Dr. Rosenzweig—, the deposition of the implanting physician—Dr. Tyler—, the depositions of plaintiff and her husband, the deposition of the surgeon who removed plaintiff's implant—Dr. Nitti—, the Altis's instructions for use, and "some articles . . . that are provided under Lancet". (ECF No. 45-2 at 24–25).

Nevertheless, Dr. Hibner admitted that he has never communicated with plaintiff, never treated plaintiff, and never conducted any sort of medical examination on plaintiff. (ECF No.

45-2 at 24). Dr. Hibner further admitted that he has not spoken with or interviewed any of the medical providers or treating physicians who cared for plaintiff. (*Id.* at 25).

In discussing plaintiff's symptoms of stress urinary incontinence after her removal surgery, Dr. Hibner opined that plaintiff "actually had the removal of mesh because of the failure of the mesh – or the erosion or exposure." (*Id.* at 146). Similarly, Dr. Hibner's report concludes with the statement that plaintiff's injuries "are a direct result of defects in the design of the Coloplast Altis device." (ECF No. 45-1 at 18). Specifically, Dr. Hibner concluded that the mesh is defective because it is "too stiff and rigid," and had "small pore[s]." (*Id.* at 16, 18).

Yet, in discussing how he concluded that the Altis's design caused plaintiff's injuries, Dr. Hibner stated that "with time, as we gain more knowledge and more evidence, it appears that the softer meshes are better for patients." (ECF No. 45-2 at 153, 154). This sentiment, that the research generally supports the use of softer mesh, does not constitute a reliable and testable method upon which Dr. Hibner drew his conclusion that the Altis's stiffer mesh necessarily caused plaintiff's injuries.

As to future harm, anytime Dr. Hibner discussed plaintiff's potential need of future medical care, he specifically attributed the likely future symptoms to Dr. Nitti's decision to leave the Altis's "anchors" inside of plaintiff when removing the mesh. (*See, e.g.*, *id.* at 164). As Dr. Hibner removes the anchors whenever he performs similar removal procedures, Dr. Nitti's decision to leave the anchors cannot be attributed to a design defect. (*See id.* at 166).

From this testimony and his report, it appears that Dr. Hibner reached his causation conclusion by reviewing plaintiff's medical history, reading her symptoms after implantation, comparing them to medical literature regarding mesh and sling implants generally, and drawing from his own experience in the field of pelvic pain and surgery to bridge the factual gaps. While this methodology may be sufficient to opine that the Altis caused plaintiff's injuries,[1] it is not enough for Dr. Hibner to testify that those injuries resulted from a defect in the Altis's *design*.

[1] Which, by withdrawing her claim for strict liability – failure to warn, plaintiff admits was a risk she was aware of before choosing to go forward with her procedure. (*See also* ECF No. 41-4 at 3) (providing that Dr. Tyler had a "lengthy discussion" with plaintiff regarding the risks of the various procedures available, and that there is a 10% failure rate with her selected procedure which may require another procedure).

To that end, the court cannot see what reliable, testable methods Dr. Hibner used to draw his specific causation conclusion based on the Altis's design. Dr. Hibner admits that he is not an expert in mesh design, the Altis's design, or the physics of mesh slings. He notes that plaintiff's complications are unique to mesh in general, but his opinion that plaintiff's injuries specifically resulted from Altis's being "too stiff and rigid" does not appear to be based on any reliable, testable methodology. Thus, his proffered causation testimony falls below the *Daubert* threshold for expert opinions.

Accordingly, Dr. Hibner may not testify regarding his opinion that the Altis's design caused plaintiff's injuries.

B. Without case specific causation testimony, plaintiff's strict liability – design defect claim fails

As previously discussed, to prevail on a claim of strict products liability for design defect, a plaintiff must prove that: 1) the defendant placed a defective product in the market; 2) the product was defective when it left the defendant's possession, and 3) the defect caused plaintiff's injuries. *Ford Motor Co. v. Trejo*, 402 P.3d 649, 653 (Nev. 2017) (citing *Shoshone Coca–Cola Bottling Co. v. Dolinski*, 420 P.2d 855, 857–58 (Nev. 1966)).

Product liability plaintiffs must establish the element of causation to prevail under any theory of liability. *Dow Chemical Co. v. Mahlum*, 970 P.2d 98, 107 (Nev. 1998), *abrogated on other grounds by GES, Inc. v. Corbitt*, 21 P.3d 11 (Nev. 2001) (citation omitted). Causation consists of "two components: actual cause and proximate cause." *Id.* (citation omitted). First, "[t]o demonstrate actual cause with respect to [the] product, the [plaintiff] had to prove that, but for the [medical device], [her] illnesses would not have occurred." *Id.* (citation omitted); *see also Goodrich & Pennington Mortgage Fund, Inc. v. J.R. Woolard, Inc.*, 101 P.3d 792, 797 (Nev. 2004). Second, proximate cause is "any cause which in natural[,] foreseeable and continuous sequence . . . produces the injury . . . without which the result would not have occurred." *Goodrich & Pennington Mortgage Fund, Inc.*, 101 P.3d at 797 (citations omitted).

"Demonstrating causation in cases involving medical products often requires expert medical testimony." *Dow Chemical Co.*, 970 P.2d 98 at 107–08 (citation omitted). Particularly,

when the injury is subjective, like pain, expert evidence is necessary. *Krause Inc. et al. v. Little*, 34 P.3d 566 (Nev. 2001).

When the testimony of a plaintiff's sole case specific causation expert is stricken, summary judgment should be granted for failure to prove causation. *See, e.g.*, *Prall v. Ford Motor Co.*, No. 2:14-cv-001313-MMD-GWF, 2017 WL 361545 (D. Nev. Jan. 24, 2017) (granting the manufacturer's motion for summary judgment because the products liability plaintiff's only causation evidence was the excludable expert opinion of his expert witness); *Flowers v. Eli Lilly & Co.*, No. 3:14-cv-00094-LRH-VPC, 2016 WL 4107681 (D. Nev. Aug. 1, 2016) (same).

Here, the court has stricken Dr. Hibner's testimony regarding specific causation from the Altis's design. Plaintiff does not provide an alternative expert to testify on the subject. (*See generally* ECF No. 54). Therefore, plaintiff's claim for strict liability – design defect fails as a matter of law.

C. Plaintiff's claims for negligence and gross negligence are subsumed by her strict liability claims

Plaintiff also alleges claims for negligence and gross negligence. (ECF No. 1 at 17, 21). Plaintiff's negligence-based claims are based on the same series of facts as her strict liability claims, particularly her claim for strict liability – failure to warn. (*See id.* ¶¶ 82,[2] 93[3]). As discussed above, plaintiff has abandoned her claims for strict liability – failure to warn and strict liability – manufacturing defect because they are unsupported by Nevada law. Further, plaintiff's claim for strict liability – design defect, fails because plaintiff cannot prove causation.

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[2] "Defendants were negligent in that they failed to exercise reasonable care in the design, manufacture, testing, inspection, processing, advertising, marketing, testing, labeling, assembling, packaging, distribution, warning, detailing, promotion and sale of its Altis[] brand mesh device."

[3] "Had [p]laintiff, her treating physician, or both known of the unreasonably dangerous risks associated with the Altis[] brand mesh device at the time of her implant surgery, such knowledge would have affected the treating physician's use of the device and Plaintiff would not have consented to the implantation of the device."

Because they are duplicative of and subsumed by the strict liability claims, summary judgment is granted as to plaintiff's negligence-based claims.[4] *See, e.g., Forest v. E.I. DuPont de Nemours & Co.*, 791 F. Supp. 1460, 1464 (D. Nev. 1992) (concluding that negligence and strict liability claims should be considered together "for purposes of considering Defendant's possible liability for failure to provide an adequate warning"); *Forest v. Vitek, Inc.*, 884 F. Supp. 378, 380 (D. Nev. 1993) (noting that "there is no practical difference between an action in negligence for breach of one's duty to warn and an action in strict liability for a product defect due to inadequate warning or labeling").

IV. Conclusion

Accordingly,

IT IS HEREBY ORDERED, ADJUDGED, and DECREED that defendants' motion to exclude the opinions and testimony of plaintiff's specific causation expert Michael Hibner M.D., Ph.D. (ECF No. 40) be, and the same hereby is, GRANTED.

IT IS FURTHER ORDERED that defendants' motion for summary judgment (ECF No. 41) be, and the same hereby is, GRANTED.

IT IS FURTHER ORDERED that all other pending motions (ECF Nos. 31; 32; 33; 34; 35; 36; 37; 38; 39; 64) be, and the same hereby are, DENIED as moot.

The clerk is instructed to enter judgment in favor of defendants on all claims and close this case accordingly.

DATED August 3, 2022.

James C. Mahan
UNITED STATES DISTRICT JUDGE

[4] Plaintiff's argument that these claims are not duplicative because courts have permitted plaintiffs to move forward to trial on both claims is unpersuasive. The court in *Forest*, 791 F. Supp. 1460, held that "[i]t is true that the two claims may differ with respect to common law defenses, especially in the area of contributory negligence. For this reason the formal dichotomy between the two causes of action should be preserved for trial." *Id.* (citation omitted). In plaintiff's cited cases, the plaintiffs proceeded to trial on both claims because the strict liability claims survived. Here, plaintiff's strict liability claims do not survive, so neither do her negligence claims.